

# First Cardiac Procedure Using the AcQMap® System by Acutus Medical® Successfully Performed in the United States

May 8, 2018

- New European/Canadian Clinical Study Initiated to Evaluate the AcQMap® System During an Atrial Fibrillation Retreatment Ablation Procedure
- Company to Present Data at the Heart Rhythm Society's 39th Annual Scientific Sessions
- FDA clearance received on additional accessory sheath catheter

CARLSBAD, CA – May 8, 2018 – Acutus Medical®, a global heart rhythm technology company, today announced that the AcQMap® High Resolution Imaging and Mapping System has been utilized for the first time in U.S. patients. The company also revealed initiation of a new clinical study to evaluate the technology during atrial fibrillation retreatment ablation procedures in Europe and Canada.

"Enabling physicians to see complex, irregular arrhythmias in real-time should provide important new insights and enable truly personalized and individualized ablation therapy planning. We hope that this unique capability, combined with the ability to quickly re-map after each ablation, will lead the way to further improvements in clinical outcomes for patients suffering from complex arrhythmias," said Vince Burgess, Chairman, President and CEO, at Acutus Medical. "Together with institutions across the country, we hope to transform the lives of people suffering from complex arrhythmias through our innovative technology and are pleased that U.S. patients now have access to AcQMap."

The AcQMap System has been used in Europe in 15 centers and in more than 500 procedures.

## **Heart Rhythm Society Meeting Participation**

Several international presentations featuring the AcQMap System will be presented at the Heart Rhythm Society's 39th Annual Scientific Sessions on May 11 from 9:30 AM EST – 12:00 PM EST in Boston, MA. The company will also be highlighting newly formed strategic collaborations with the goal of improving patient care and physician experience in electrophysiology.

## **Clinical Trials**

Acutus also announced today the first enrollment in the RECOVER AF clinical study. The study is a prospective, single-arm, multi-center trial designed to provide clinical data regarding the use of the AcQMap System during first or second atrial fibrillation retreatment ablation procedures. The RECOVER AF study will enroll up to 100 patients in Europe and Canada.

The first procedure was successfully completed by Tim Betts, MD, MBChB, FRCP at John Radcliffe Hospital, Oxford University Hospitals in Oxford, United Kingdom.

"In patients undergoing re-do ablation for persistent AF we often need to look beyond simple pulmonary vein isolation and identify additional electrophysiological mechanisms driving the arrhythmia," said Dr. Betts. "In this particular patient, I was able to map both the left and right atriums, direct my ablation strategy at rotational activity and focal firing and acutely terminate the longstanding persistent AF back to sinus rhythm. Seeing the System's immediate impact has made me optimistic that this patient will now be free of AF."

#### FDA Clearance

The FDA has also cleared the AcQRef™ Introducer Sheath for use in percutaneous procedures to facilitate venous access from the lower extremities for introduction of catheters and other devices, and to sense intravenous signals. Strategically placed electrodes along the introducer shaft can be used as a cardiac electrical reference when used in conjunction with the AcQMap System.

### About the AcQMap High Resolution Imaging and Mapping System

The AcQMap High Resolution Imaging and Mapping System detects and displays both standard voltage-based and higher resolution dipole density-based (charge-source) maps of the heart. The AcQMap System uniquely combines ultrasound anatomy construction with an ability to map the electrical-conduction of each heartbeat to identify complex arrhythmias across the entire atrial chamber. Following each ablation treatment, the heart can be re-mapped in seconds to continually visualize any changes from the prior mapping.

## **About Acutus Medical**

Acutus Medical is a global heart rhythm technology company transforming the way electrophysiologists diagnose and treat cardiac arrhythmias. Acutus Medical is a privately held company located in Carlsbad, CA. To learn more, visit <a href="https://www.acutusmedical.com">https://www.acutusmedical.com</a>.

# **Forward Looking Statements**

This press release contains forward-looking statements that are subject to many risks and uncertainties. Forward-looking statements include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned product development, and clinical and regulatory milestones. We may use terms such as "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained herein, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this press release. As a result of these factors, we cannot assure you that the forward-looking statements in this press release will prove to be accurate. Acutus

Medical expressly disclaims any intent or obligation to update these forward-looking statements, except as required by law.

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